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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,616	10/17/2001	Frances E. Lund	AP33438 068443.0106	8224

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BAKER & BOTTS  
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NEW YORK, NY 10112

EXAMINER
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BELYAVSKIY, MICHAIL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/982,616	<b>Applicant(s)</b> LUND ET AL.	
	<b>Examiner</b> Michail A Belyavskyi	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

## DETAILED ACTION

1. *Claims 1-34 are pending.*

### ***Restriction Requirement***

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-7, 15 and 16 drawn to an isolated nucleotide sequence encoding polypeptide; host cells and methods of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
  - II. Claims 8-12 drawn to an isolated polypeptide, classified in Class 530, subclass 350.
  - III. Claim 13 drawn to a fusion protein, comprising a fragment of a SM38 protein, classified in Class 530, subclass 350
  - IV. Claim 14 drawn to antibody which is capable of binding a SM38 protein, classified in Class 530, subclass 387.1.
  - V. Claims 17, 19 and 20 drawn to a method for identifying a compound that activates CD38 enzyme activity, wherein CD38 ADP-ribosyl cyclase activity is measured classified in Class 435, subclass 68.1.
  - VI. Claims 17, 19 and 21 drawn to a method for identifying a compound that activates CD38 enzyme activity, wherein cADPR is measured classified in Class 435, subclass 7.1.
  - VII. Claims 17, 19 and 22 drawn to a method for identifying a compound that activates CD38 enzyme activity, wherein NAADP is measured classified in Class 435, subclass 7.1.
  - VII. Claims 17, 19 and 23 drawn to a method for identifying a compound that activates CD38 enzyme activity, wherein intracellular calcium levels are measured classified in Class 435, subclass 325.
  - VIII. Claims 17, 19 and 24 drawn to a method for identifying a compound that activates CD38 enzyme activity, wherein CD38 mediated cell migration is measured classified in Class 435, subclass 375.

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- IX. Claims 18, 19 and 20 drawn to a method for identifying a compound that inhibits CD38 enzyme activity, wherein CD38 ADP-ribosyl cyclase activity is measured classified in Class 435, subclass 68.1.
- X. Claims 18, 19 and 21 drawn to a method for identifying a compound that inhibits CD38 enzyme activity, wherein cADPR is measured classified in Class 435, subclass 7.1.
- XI. Claims 18, 19 and 22 drawn to a method for identifying a compound that inhibits CD38 enzyme activity, wherein NAADP is measured classified in Class 435, subclass 7.1.
- XII. Claims 18, 19 and 23 drawn to a method for identifying a compound that inhibits CD38 enzyme activity, wherein intracellular calcium levels are measured classified in Class 435, subclass 325.
- XIII. Claims 18, 19 and 24 drawn to a method for identifying a compound that inhibits CD38 enzyme activity, wherein CD38 mediated cell migration is measured classified in Class 435, subclass 375.
- XIV. Claim 25 drawn to a method for identifying a compound that modulates CD38 classified in Class 435, subclass 7.1.
- XV. Claims 26 and 28, drawn to a method for identifying a compound that activates CM38 enzyme activity, wherein cADPR is measured classified in Class 435, subclass 7.1.
- XVI. Claims 26 and 29 drawn to a method for identifying a compound that activates CM38 enzyme activity, wherein NAADP is measured classified in Class 435, subclass 7.1.
- XVII. Claims 26 and 30 drawn to a method for identifying a compound that activates CM38 enzyme activity, wherein intracellular calcium levels are measured classified in Class 435, subclass 325.
- XVIII. Claims 26 and 31 drawn to a method for identifying a compound that activates CM38 enzyme activity, wherein CD38 mediated cell migration is measured classified in Class 435, subclass 375.

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- XIX. Claims 27 and 28 drawn to a method for identifying a compound that inhibits CM38 enzyme activity, wherein cADPR is measured classified in Class 435, subclass 7.1.
  - XX. Claims 27 and 29 drawn to a method for identifying a compound that inhibits CM38 enzyme activity, wherein NAADP is measured classified in Class 435, subclass 7.1.
  - XXI. Claims 27 and 30 drawn to a method for identifying a compound that inhibits CM38 enzyme activity, wherein intracellular calcium levels are measured classified in Class 435, subclass 325.
  - XXII. Claims 27 and 31 drawn to a method for identifying a compound that inhibits CM38 enzyme activity, wherein CD38 mediated cell migration is measured classified in Class 435, subclass 375.
  - XXIII. Claim 32 drawn to a method for identifying a compound that modulates CM38 classified in Class 435, subclass 7.1.
  - XXIV. Claim 33 drawn to a method of modulating the migration activity of cells, comprising contacting cells with CD38 inhibitor, classified in Class 435, subclass 375.
  - XXV. Claim 34 drawn to a method of modulating the migration activity of cells, comprising contacting cells with CD38 activator, classified in Class 435, subclass 375.
3. Groups I- IV are different products. Nucleic acids, polypeptides, fusion proteins and antibodies to the polypeptides differ with respect to their structures and physicochemical properties and mode of action which require non-coextensive searches. Therefore, they are patentably distinct.
4. Groups V-XXV are different methods. These invention differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.
5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

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6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. A telephone call was made to Carmella Stephens on August 29, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.  
Patent Examiner  
Technology Center 1600  
September 8, 2003

  
CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600